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10/019,220	05/16/2002	Kim King Tong Lau	117-373	6272

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,220

Applicant(s)

LAU ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-50, 62, 64 and 65 is/are allowed.
- 6) ☒ Claim(s) 51-54, 61, 63 and 67-69 is/are rejected.
- 7) ☒ Claim(s) 55-60 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the Rejections pending since the Office action of June 26, 2006

1. All previous rejections are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 51, and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikeda et al. ("An Efficient Method for Entrapping Ionic Mediators in the Enzyme Layer of Mediated Amperometric Biosensors," Agric. Biol. Chem. 52(12), 3187-3188, 1988) ("Ikeda").

Addressing claim 51, Ikeda discloses an amperometric sensor suitable for determining the concentration of hydrogen peroxide in a sample (implied since peroxidase is included in the sensor and H_2O_2 is measured – first sentence in the last paragraph in the second column on page 3187), the sensor comprising a ferricyanide compound (first sentence in the last paragraph in the second column on page 3187), which ferricyanide, in reduced form functions as a mediator "selective" for hydrogen peroxide (since this is a property of reduced ferricyanide it is inherent it. Furthermore, this property is implied since H_2O_2 is measured – first sentence in the last paragraph in the second column on page 3187). Ikeda does not mention whether the ferricyanide is "bound" to a polymer; however, this is implied since Ikeda states, "The results indicate that Fe(II) is entrapped in a high concentration in the DE-Sdx layer at the dialysis membrane-DE-Sdx-Fe(II)-CPE." See the first full paragraph in the second column on page 3187.

Addressing claim 67, for the claimed "cartridge" the examiner has construed the implied beaker or fluidic container as such a cartridge. See the last sentence in the first column on page 3187 bridging to the second column.

Addressing claims 68 and 69, peroxidase, for example, is disclosed. See the first sentence in the last paragraph in the second column on page 3187.

4. Claims 51, 53, 54, and 67-69 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited JPO English language computer translation of Goto et al. (JP 09-101281 A) ("Goto").

Addressing claim 51, Goto discloses an amperometric sensor suitable for determining the concentration of hydrogen peroxide in a sample (implied since glucose concentration is indirectly determined by measuring H_2O_2 produced by glucose oxidase acting on the sample – paragraph [0018] in Detailed Description). Also, see page 8 of Applicant's specification, which discloses indirectly measuring glucose concentration by measuring peroxide concentration, and claim 54), the sensor comprising a ferricyanide compound (paragraph [0016] in Detailed Description; claim 3; paragraph [0022] in Detailed Description; and paragraph [0016] of Means), which ferricyanide, in reduced form functions as a mediator "selective" for hydrogen peroxide (since this is a property of reduced ferricyanide it is inherent it. Furthermore, this property is implied since H_2O_2 is measured – paragraph [0018] in Detailed Description and [Effect of the Invention] in Effect of the Invention). Goto does not mention whether the ferricyanide is "bound" to a polymer; however, this is implied since the ferricyanide is part of the photo-curing resin

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film. See claim 3; paragraphs [0004], [0016], and [0023] in Detailed Description; and [Means for Solving the Problem] and paragraph [0017] in Means.

Addressing claims 53 and 54, for the additional limitations of these claims see paragraphs [0008]-[0018] of the Detailed Description.

Addressing claim 67, the claimed “cartridge” is defined by at least the insulating substrate on which the electrodes and reagent are placed. See paragraphs [0003] and [0004] of the Detailed Description.

Addressing claims 68 and 69, for the additional limitations of these claims see paragraphs [0003] and [0004] of the Detailed Description.

5. Claims 51, 53, and 67-69 are rejected under 35 U.S.C. 102(e) as being anticipated by newly cited Nakamura et al. (US 4,224,125) (“Nakamura”)

Addressing claim 51, Nakamura discloses an amperometric sensor suitable for determining the concentration of hydrogen peroxide in a sample (implied since glucose concentration is indirectly determined by measuring H₂O₂ produced by glucose oxidase acting on the sample – col. 1:34-55. Also, see page 8 of Applicant’s specification, which discloses indirectly measuring glucose concentration by measuring peroxide

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concentration, and claim 54), the sensor comprising a ferricyanide compound (col. 10:20-25), which ferricyanide, in reduced form functions as a mediator “selective” for hydrogen peroxide (since this is a property of reduced ferricyanide it is inherent it. Furthermore, this property is implied since H_2O_2 is measured – col. 10:33-38 and col. 1:34-55). Nakamura does not mention whether the ferricyanide is “bound” to a polymer; however, this is implied since the ferricyanide absorbed to a cation-exchange resin (col. 10:20-25).

Addressing claims 53 and 54, for the additional limitations of these claims see col. 10:20-45.

Addressing claim 67, the claimed “cartridge” can be construed to be either the fluid container in which the sensor (7) has been placed in Figure 2 or the sensor assembly itself, which is shown in Figure 1.

Addressing claims 68 and 69, for the additional limitation of this claim see col. 10:20-32.

Claim Rejections - 35 USC § 103

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 51-54, 61, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited JPO English language computer translation of Yamamoto et al. (JP 07-103933 A) ("Yamamoto") in view of Chen et al. ("Redox electrode for monitoring oxidase-catalyzed reactions," *Clinica Chimica Acta*, 193 (1990) 187-192) ("Chen").

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Addressing claim 51, Yamamoto discloses an amperometric sensor for determining concentration of analyte in a sample, the sensor comprising a ferricyanide compound bound to a polymer, which ferricyanide, in reduced form, functions as a mediator. See the abstract and Effect of the Invention.

Yamamoto does not mention determining the concentration of hydrogen peroxide; however, Yamamoto does disclose that the invention (ferricyanide bound to a polymer in a sensor) may be used with a large variety of enzymes, such as cholesterol esterase, cholesterol oxidase, glucose oxidase, and alcohol oxidase. See paragraph [0017] of Detailed Description and paragraph [0017] of Example. Chen discloses that it was known at the time of the invention to use peroxidase with ferricyanide for electrochemically measuring hydrogen peroxide concentration. See page 187. Thus, it would have been obvious to one with ordinary skill in the art at the time of the invention that the invention of Yamamoto could be adapted to measure hydrogen peroxide just by using peroxidase in the sensor. Thus, barring evidence to the contrary, such as unexpected results, the choice of analyte, such as hydrogen peroxide, is simply a matter of selecting the appropriate enzyme for use in the sensor of Yamamoto.

Addressing claim 52, Yamamoto discloses that the polymer may be acrylamide. See paragraph [0015] of the Detailed Description.

Addressing claims 53 and 54, for the additional limitations of these claims see paragraphs [0006]-[0013] and [0017] of the Detailed Description.

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Addressing claim 61, for the additional limitation of this claim see, for example, paragraphs [0012] and [0015] in the Detailed Description and paragraph [0013] and [0015], which discloses using for the polymer polylysine or polyornithine, in each of which the polymer chain side group is an amino side group. See the ACS File Registry entries for polylysine or polyornithine. Since Yamamoto discloses that the polymer is ionized (“ionicity”) one with ordinary skill in the art would interpret this to mean that the amino groups have an additional substituent and so comprise a quaternary ammonium ion.

Addressing claim 67, for the claimed “cartridge” see Drawing 2, which shows the sensor housing assembly.

Addressing claims 68 and 69, for the additional limitation of this claim see paragraphs [0009], [0010], and [0017] of the Detailed Description

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 63 requires that the ferricyanide compound have a solubility of from 2000 mg/L to 20,000 mg/L in pure water. However, claim 51, from which claim 63 depends, requires that the ferricyanide compound be bound to the polymer. These two limitations appear to be inconsistent, if not contradictory.

Double Patenting

11. Claim 66 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 65. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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12. Claim 69 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 68. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

13. Claims 44-50, 62, and 64-66 are allowed.

14. Claims 55-60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claim 63 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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16. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 44: the combination of limitations requires that "X" in the formula for the ferricyanide compound be an alkyl substituted phosphonium ion.

In Svitel the "X"s are alkyl substituted ammonium ions or alkyl substituted pyridinium ions.

In Nanba the "X"s are alkyl substituted ammonium ions or alkyl substituted pyridinium ions.

In Shiiki the "X" is an alkyl substituted ammonium ion.

In Ikeda, Goto, Nakamura, and Yamamoto the "X"s are potassium ions.

b) Claims 45-50, 62, and 64-66 depend directly or indirectly from allowable claim 44.

c) Claim 55: the combination of limitations requires that at least one "X" of the ferricyanide formula be non-metallic.

In Ikeda, Goto, Nakamura, and Yamamoto the ferricyanide compound is potassium ferricyanide. In Ikeda see the first sentence in the second paragraph in the first column on page 3187 (note "potassium ferricyanide"). In Goto see claim 1 and paragraph [0004] of the Detailed Description (note "potassium

ferricyanide"). In Yamamoto col. 10:20-25 (note "potassium ferricyanide"). see paragraphs [0009] and [0012] and the abstract (note "potassium ferricyanide").

d) Claim 56: the combination of limitations requires that each "X" of the ferricyanide formula be a quaternary ammonium ion complying with a specified formula.

In Ikeda, Goto, Nakamura, and Yamamoto the ferricyanide compound is potassium ferricyanide. In Ikeda see the first sentence in the second paragraph in the first column on page 3187 (note "potassium ferricyanide"). In Goto see claim 1 and paragraph [0004] of the Detailed Description (note "potassium ferricyanide"). In Yamamoto col. 10:20-25 (note "potassium ferricyanide"). see paragraphs [0009] and [0012] and the abstract (note "potassium ferricyanide").

e) Claim 57 depend from allowable claim 56.

f) Claim 58: the combination of limitations requires that each "X" of the ferricyanide formula be a phosphonium ion complying with a specified formula.

In Ikeda, Goto, Nakamura, and Yamamoto the ferricyanide compound is potassium ferricyanide. In Ikeda see the first sentence in the second paragraph in the first column on page 3187 (note "potassium ferricyanide"). In Goto see

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claim 1 and paragraph [0004] of the Detailed Description (note "potassium ferricyanide"). In Yamamoto col. 10:20-25 (note "potassium ferricyanide"). see paragraphs [0009] and [0012] and the abstract (note "potassium ferricyanide").

g) Claims 59 and 60 depend directly or indirectly from allowable claim 55.

✿

h) Claim 63: the combination of limitations requires ferricyanide compound have a solubility of from 2000 mg/L to 20,000 mg/L in pure water. In Ikeda, Goto, Nakamura, and Yamamoto the ferricyanide compound is potassium ferricyanide. The solubility of potassium ferricyanide ranges from 304,000 mg/L at 0°C to 1,304,000 mg/L at 100°C. See Friend et al. ("the solubility of potassium ferricyanide in water between 0° and 100°.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Alex Noguera", is positioned above the printed name.

Alex Noguera
Primary Examiner
AU 1753
February 20, 2006